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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/932,227	09/17/97	FOSSEL	E

EXAMINER

IM12/0323

ERIC T FOSSEL
17 SUNSET VIEW ROAD
S HERO VT 05486

ART UNIT	PAPER NUMBER
1711	2

MULLIS, J

DATE MAILED: 03/23/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on Filing 9-17-97.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-19, 21-32 is/are rejected.

☒ Claim(s) 20 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

* U.S. GPO: 1996-410-238/40050

Applicant is reminded that any references cited at pages 1 and 2 of the instant specification which are material to patentability need be submitted in accordance with applicant's duty of disclosure.

Claim 6 contains the misspelling "th" at line 2 of this claim. Correction is required. Claim 18 contains the misspelling "acondom". Correction is required.

Claims 2-11, 13, 14, 16, 17-19 and 24-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 lacks antecedent basis in claim 9 in that claim 9 is restricted to the materials recited therein since claim 9 recites "consists of" and therefore excludes choline chloride. Claim 32 similarly lacks antecedent basis in claim 31.

Claim 31 lacks antecedent basis in claim 21 in that claim 31 recites a cream while claim 21 does not.

The phrase "or other topical preparation" throughout the claims is unclear in that the preparations cited previous to the "topical preparation" are not necessarily topical and therefore it is unclear whether it is intended that all the preparations in claims reciting "or other topical preparation" are meant to be topical preparations also.

It is not clear what is intended by "L-arginine a salt". This term is not art recognized.

The term "little" as appears in at least claim 4 is subjective and therefore unclear.

The term "like" is unclear in that it cannot objectively be determined what materials are like another.

Applicant's claims recite numerous groups of material without stating whether or not these materials are to be used in combination or as alternatives. Note for instance claim 7 which recites "L-arginine a salt a complex thereof" without reciting whether or not these materials are to be used in combination or as alternatives.

"The cream" of claim 9 lacks antecedent basis in claim 1.

The term "equivalent" which is recited in at least claim 18 is unclear in that it is subjective as to when a material is an equivalent of another material.

Claims 26 and 27 contain the words "little" and "like". For the reasons set out above, these terms are unclear.

The terms "glyceryl stearate SE" and "propylene glycol stearate SE" are not art recognized and are therefore unclear. If these terms are tradenames, tradenames are unacceptable in patent claims since the meaning of tradenames may change with the whim of the manufacturer.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 9 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Saavedra et al. (USP 5,632,981).

Saavedra et al. disclose a process for treating impotence in which a nitric oxide releasing material is incorporated into a condom (column 10 lines 20-35). The composition may be in the form of liposomes in a gel or patch at column 9 lines 51-65 and

applied topically (column 11 lines 16-26) and may be non-aqueous (note the paragraph bridging columns 11 and 12). Since nitric oxide increases blood flow, increase of blood flow to tissue would be inherent in the process. Phosphate buffer (an inherently salt containing material) may be added at column 12 lines 48-56, or "saline" may be added at column 11 lines 40-52.

Claims 1, 7, 9, 12, 21, 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Garfield et al. (USP 5,698,738).

Garfield et al. disclose a process for healing wounds, treating impotence and restoring hair growth by topical application of an active ingredient. Note column 6 line 40 - column 5 line 50. The active ingredient is a nitric oxide donor at column 6 lines 4-22. Excipients such as salt solutions for influencing osmotic pressure and vegetable oils may be added and the composition may be in the form of transdermal patches at column 8 line 65 - column 9 line 45. Since application of nitric oxide increases blood flow, increasing blood slow would be inherent in the reference.

Claims 1 and 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Gray et al. (USP 5,714,472).

Gray et al. disclose a nutritional formulation for promoting wound healing which contains arginine. Note the second paragraph on page 6. Choline may be added. Note the Table on page 9.

Claims 1-9, 11-19 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al., cited above in view of Hechtman (USP 5,595,753), Kaesemeyer (USP 5,543,430), Cooke et al. (USP 5,428,070) and Saavedra et al., cited above.

Hechtman discloses that arginine may be applied topically to enhance nitric oxide production in tissue requiring such (Abstract, column 9 lines 56-61) and is taught to be particularly safe in comparison to other nitric oxide precursor substances (column 2 lines 9-18).

Kaesemeyer discloses that arginine/nitroglycerin is more effective for increasing nitric oxide levels in tissues requiring such and materials which directly release nitric oxide. Note the Abstract.

Cooke et al. disclose that arginine glutamate functions to release nitric oxide in tissues requiring such (column 4 lines 17-30).

It would have been obvious to a practitioner having an ordinary skill in the art at the time of the invention to use the arginine of Hechtman in the process of Garfield et al. motivated by Hechtman's disclosure that arginine functions to release nitric oxide, as do the materials of Garfield et al. and by the benefit of increased safety as disclosed by Hechtman and the expectation of extending the benefit of increased safety to the

composition and process of Garfield et al., absent any showing of surprising or unexpected results.

It would have been obvious to a practitioner having an ordinary skill in the art at the time of the invention to use the arginine/nitroglycerin of Kaesemeyer as the nitric oxide increasing substance material in the process of Garfield et al. motivated by the expectation that the arginine/nitroglycerin combination of Kaesemeyer would be more effective than the nitric oxide increasing materials of Garfield et al., absent any showing of surprising or unexpected results.

It would have been obvious to a practitioner having an ordinary skill in the art at the time of the invention to use the arginine glutamate of Cooke et al. in the process of Garfield et al. motivated by Cooke et al.'s disclosure that arginine glutamate functions to release nitric oxide in tissue and by the consequent expectation that the arginine glutamate of Cooke et al. would function as well as the nitric oxide releasing materials of Garfield et al. in the process of Garfield et al., absent any showing of surprising or unexpected results.

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant should also correct the unmatched right parentheses in claim 20.

Claims 31-32 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112 and to include all of the limitations of the base claim and any intervening claims.

Garfield et al. (USP 5,698,738), cited of interest discloses that nitric oxide donors may be added to wound healing and hair growth compositions at column 6 lines 49-50.

Murrell (PCT/US 95/12503, cited of interest discloses that nitric oxide donors may be added to wound healing compositions.

Weuffen et al. (USP 5,629,002), cited of interest discloses that amino acids may be present as active ingredients in hair restoring compositions. Note the Abstract.

Keefer et al. (USP, cited of interest discloses that nitric acid donating materials may be incorporated into condoms. Note the Abstract.

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

JEFFREY C. MULLIS
PRIMARY EXAMINER
GROUP 1200 / 1711

J. Mullis:cdc
March 21, 1998